REMARKS

In response to the Office Action mailed March 6, 2001, the present application has been carefully reviewed and amended. Entry of the present amendments and reconsideration of the application is respectfully requested.

Rejections Under 35 U.S.C. §112

Claim 22

Claim 22 stands rejected under 35 U.S.C. §112, second paragraph, for the recitation of "the corrective procedure." Claim 22 has been amended to recite "an apparatus for determining an intra procedural blood flow in a corrective procedure." Therefore, the recitation of "means for effecting the corrective procedure" is believed to comply with 35 U.S.C. §112.

Rejections Under 35 U.S.C. §103

Claims 1-7, 9-20 and 22-23

Claims 1-7, 9-20 and 22-23 stand rejected under 35 U.S.C. §103 as being unpatentable over Schneiderman (U.S. Patent No. 5,046,503) in view of Quinn ('654).

Claims 1, 9, 15, 16, 19, 20, 22 and 25

With respect to Claims 1, 9, 15, 16, 19, 20, 22 and 25, Examiner Szmal relies upon Schneiderman to disclose the use of an angioplasty autoperfusion catheter flow measurement method that discloses the use of an angioplasty balloon for reducing a stenosis. Schneiderman is further relied on to disclose the use of measuring blood flow through the use of an ultrasonic sensor. Examiner Szmal relies upon Quinn to disclose a blood property change port and downstream sensor and means for calculating a flow rate. The examiner asserts it would thus be obvious to modify Schneiderman in view of Quinn to measure blood flow through the use of thermodilution, since the blood flow within a lumen can be measured by Doppler techniques as well as through thermodilution. (Paper 13, pages 3-4)

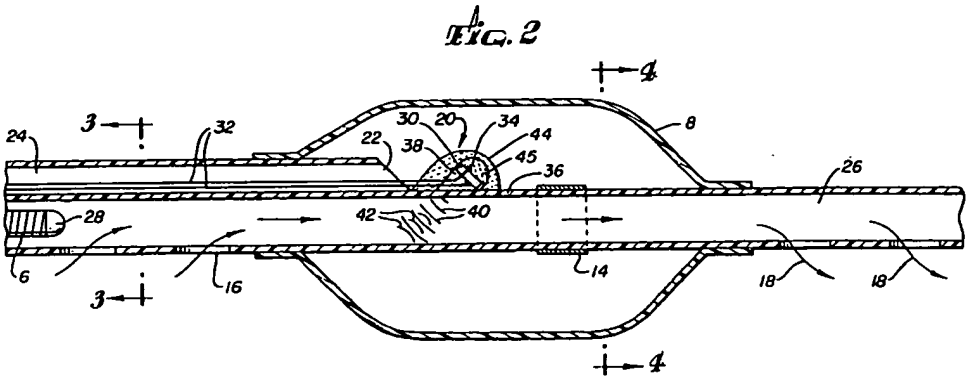
Schneiderman

Schneiderman discloses an angioplasty autoperfusion catheter flow measurement apparatus having a balloon catheter with an autoperfusion lumen incorporated therein. The

autoperfusion of Schneiderman is the flow through the catheter, caused by the inflated balloon. Specifically:

> "In order to increase the amount of time available for balloon inflation without causing these undesirable side effects, autoperfusion catheter systems have been developed which incorporate a conduit for blood flow past the balloon subsystem in the distal end of the catheter. Such autoperfusion catheters incorporate an entry upstream of the balloon, a lumen within the portion of the catheter incorporating the balloon, an exit to the lumen located near the distal end and downstream of the balloon." (Col. 1, lines 36-45)
>
> "In order to significantly increase the allowable inflation time without causing such damage, autoperfusion catheters have been developed which incorporate a means of moving blood past the inflated balloon through the use of a lumen or channel internal to the catheter and having blood flow orifices communicating with the arterial lumen. The complex nature of such autoperfusion, the possibility of failure or clogging of the autoperfusion channel and the possibility that, for a variety of reasons, the channel may not be providing an adequate flow of blood to prevent angina or heart damage, have combined to indicate that it would be very useful to provide a reliable method to *monitor the blood flow rate through the autoperfusion channel.*" [emphasis added] (Col. 2, lines 33-46)
>
> "According to the present invention, a flow measurement system is incorporated in the dilatation catheter to thereby measure the flow of blood through the autoperfusion channel." (Col. 2, lines 47-49)
>
> " A typical autoperfusion balloon dilatation catheter incorporates an autoperfusion channel within the balloon section that is connected to vents in the catheter wall located proximally and distally from the balloon. Thus, *when the balloon is inflated to displace the plaque from the central portion of the artery, blood flows through the autoperfusion channel and provides blood flow to the muscle being served by the artery.* Unfortunately, previous applications of autoperfusion catheters did not provide an indication of the blood flow through the autoperfusion channel..." [emphasis added] (Col. 4, lines 26-36)
>
> "The present invention provides a means of directly indicating the flow velocity *of blood within the autoperfusion channel* ... [emphasis added] (Col. 4, lines 39-44)

Specifically, after the Schneiderman balloon is inflated, the stenosis is expanded by the angioplasty catheter. A flow measurement system is incorporated into the dilation catheter to measure the flow of blood *through* the autoperfusion catheter when the balloon is expanded. That is, Schneiderman allows the physician to monitor the blood flow velocity through the autoperfusion channel while the balloon is inflated.



That is, as seen in Figure 2 of Schneiderman, blood flow occurs through the autoperfusion lumen 26 only upon inflation of the balloon. "The inflation lumen 24 is in communication with the inside of balloon 8 through inflation lumen 22 while autoperfusion lumen 26 acts as an autoperfusion channel between port 16 and 18 to thereby bypass balloon 8 when it is inflated during an angioplasty procedure." (Col. 5, Lines 54-59). Thus, Schneiderman provides a flow measurement only within the autoperfusion channel and during the angioplasty procedure.

Schneiderman does not identify the flow defined by the relevant vascular passage or vessel, but rather the flow through and within the catheter. The flow within the catheter does not provide information as to the flow defined by the damaged/corrected vessel.

In contrast, the present claims are directed to a flow outside of the catheter and thus permit measurement of flow in the vessel before and after the procedure without requiring removal of the catheter.

The proposed modification of Schneiderman to employ thermodilution techniques within the autoperfusion lumen 26 is in opposite to the structure of the present claims. That is, it would be expressly contrary to Schneiderman to measure the blood flow external of the catheter.

Claim 1

Amended Claim 1 recites in part, "a blood property change port located to alter *a blood property outside the catheter* and a downstream sensor spaced from the port for producing a signal corresponding to the blood property in blood flow between the catheter and the vessel." [emphasis added]

As the primary reference Schneiderman expressly requires and determines a blood flow within the autoperfusion channel of the catheter and only when the vessel is occluded by the balloon, applicant submits the Schneiderman cannot be modified to "alter a blood property outside the catheter ... produc[e] a signal corresponding to the blood property in blood flow between the catheter and the vessel." That is, as the flow through the Schneiderman autoperfusion channel occurs only when there is no flow between the catheter and the vessel, applicant submits Claim 1, as amended is in condition for allowance.

Claim 2

Examiner Szmal relies upon Schneiderman to disclose use of a blood property sensor placed within the lumen of the catheter inside the angioplasty balloon. Thus, the examiner concludes it would have been obvious "to recognize that the sensor of Schneiderman located such that it minimizes wall effects."

Just as Examiner Szmal asserts the blood property sensor of Schneiderman is placed within the lumen of the catheter, the Schneiderman blood property sensor is thus shielded from wall effects. Were this logic followed to the conclusion, Schneiderman would thus teach to locate the blood property sensor within the catheter, thus confirming monitoring the blood within the catheter, rather than blood external to the catheter and thus, further exposed to wall effects of the vessel. Therefore, applicant respectfully submits the rejection of Claim 2 cannot be sustained.

As Claims 3-7 depend from Claim 1 and include all limitations thereof, these claims are also in condition for allowance.

Claim 9

Independent Claim 9 as amended, recites in part "a sensor spaced from the blood property change port for providing a signal corresponding to a *change in a blood property external to the stenosis reducing catheter.*"

As Schneiderman discloses and specially operates only upon blood flow through the auto perfusion channel, applicant submits the modification of Schneiderman to provide the present limitations of Claim 9 cannot be sustained.

As Claims 10-14 depend from Claim 9 and include all limitations thereof, these claims are also in condition for allowance.

Claim 15

Independent Claim 15 recites in part "a dilution indicator port for passing a dilution indicator therethrough to pass from a catheter and a downstream sensor for producing a signal corresponding to passage of the dilution indicator external to the catheter."

As this external to the catheter introduction of dilution indicator and signal corresponding to passage of the dilution indicator external to the catheter are inoperable in Schneiderman, applicant respectfully submits Claim 15 is in condition for allowance.

Claim 16

Independent Claim 16 recites in part "introducing a first change in a blood property in a blood flow outside the catheter and upstream of the blood property sensor."

As discussed, Schneiderman teaches the measuring of blood flow through the autoperfusion lumen within the catheter and in fact, Schneiderman only functions when the balloon is inflated. There is thus, no flow in the vessel between the outside of the catheter and the vessel wall when there is flow through the autoperfusion channel of Schneiderman. As the proposed modification of Schneiderman would be contrary to the express teachings of Schneiderman, Applicant submits Claim 16 is in condition for allowance.

As Claim 17 and 18 depend from Claim 16 and include all limitations thereof, these claims are also in condition for allowance.

Claim 19

Independent Claim 19 recites in part "introducing a first blood property change into a blood flow outside the catheter."

As previously discussed, the proposed modification of the primary reference Schneiderman provides at best, measurement of a flow through an autoperfusion lumen and fails to disclose or suggest and, applicant respectfully submits, is expressly contrary to the measurement of flow outside or external to the catheter. Therefore, the rejection of Claim 19 cannot be sustained.

Claim 20

Independent Claim 20 recites in part "a catheter having ... a dilution indicator introduction port located to pass a dilution indicator from the catheter."

As previously discussed, the proposed modification of Schneiderman does not disclose or suggest the passing of a dilution indicator from the catheter. Therefore, the rejection of Claim 20 cannot be sustained.

Claim 22

Independent Claim 22 recites in part "a blood parameter altering section on the catheter located to alter a blood parameter external to the catheter . . . and a blood parameter sensor connected to the catheter and spaced from the blood parameter altering section to sense the altered blood parameter external to the catheter."

As Schneiderman expressly is directed to the flow through the autoperfusion lumen within the catheter, applicant submits the proposed modification cannot sustain rejection of Claim 22 as amended.

As Claims 23 and 24 depend from Claim 22 and include all limitations thereof, these claims are also in condition for allowance.

Claim 25

Independent Claim 25 has been amended to recite in part "locating a blood parameter altering section in the vessel to alter a blood parameter in a blood flow contacting vessel."

As the primary reference Schneiderman teaches only the measurement of flow in a autoperfusion lumen, Claim 25 is in condition for allowance.

As Claims 26-29 depend from Claim 25 and include all limitations thereof, these claims are also in condition for allowance.

Claims 34 and 35

Claims 34 and 35 corresponding to previously allowed Claims 8 and 21, now rewritten in independent form.

Information Disclosure Statement

Applicant request confirmation of the Information Disclosure Statement mailed January 26, 2001, a copy of which is attached.

Therefore, applicant respectfully submits all the pending claims, Claims 1-35 are in condition for allowance and such action is earnestly solicited. If, however, the examiner feels that any further issues remain he is cordially invited to contact the undersigned.

Respectfully submitted,

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Date: July 19, 2001

Version with markings showing changes

1. (Twice Amended) An apparatus for determining a blood flow in a vessel, comprising:

(a) an elongate catheter having a stenosis reducing member, a blood property change port located to alter a blood property outside the catheter and a downstream sensor spaced from the port for producing a signal corresponding to ~~a~~ the blood property in blood flow between the catheter and the vessel.

2. The apparatus of Claim 1, wherein one of the sensor and the catheter is configured to locate the sensor with respect to the vessel to minimize wall effects.

3. The apparatus of Claim 1, further comprising a controller operably connected to the sensor to calculate a flow rate corresponding to the signal from the downstream sensor.

4. The apparatus of Claim 1, wherein the blood property change port includes an aperture for introducing a blood property variant.

5. The apparatus of Claim 1, wherein the blood property change port and the sensor are spaced by a sufficient distance to substantially mix a dilution indicator introduced through the port and the blood flow.

6. The apparatus of Claim 1, wherein the blood property change port includes one of a heat sink and a heat source for creating a local temperature gradient.

7. The apparatus of Claim 1, wherein the signal from the sensor corresponds to a blood flow in the vessel.

8. The apparatus of Claim 7, wherein the correspondence relates blood flow to $=\frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve.

9. (Once Amended) A stenosis reducing catheter, comprising:

(a) a stenosis reducing member selectively actuatable to reduce stenosis in a vessel;

(b) a port for inducing a blood property change to blood flowing external to the stenosis reducing catheter; and

(c) a sensor spaced from the blood property change port for providing a signal corresponding to a change in a blood property external to the stenosis reducing catheter. -

10. The catheter of Claim 9, wherein one of the sensor and the catheter is configured to locate the sensor with respect to the vessel to minimize wall effects.

11. The catheter of Claim 9, further comprising a controller operably connected to the sensor to calculate a flow rate corresponding to the signal from the downstream sensor.

12. The catheter of Claim 9, wherein the port includes an aperture for introducing a blood property variant.

13. The catheter of Claim 9, wherein the blood property change port and the sensor are spaced by a sufficient distance to substantially mix a dilution indicator introduced through the port and the blood flow.

14. The catheter of Claim 9, wherein the port includes one of a heat sink and a heat source for creating a local temperature gradient.

15. (Twice Amended) An apparatus for determining blood flow, comprising:

(a) a dilution indicator source;

(b) a catheter connectable to the dilution indicator source, the catheter having means for performing a vascular corrective procedure, a dilution indicator port for passing a dilution indicator therethrough to pass from the catheter and a downstream sensor for producing a signal corresponding to passage of the dilution indicator external to the catheter; and

(c) a controller connected to the dilution indicator source and the sensor for calculating a blood flow in response to the signal from the sensor.

16. (Twice Amended) A method for quantitatively measuring a reduced stenosis induced flow change, comprising:

(a) inserting a catheter and a blood property sensor into a vessel having a blood flow corresponding to the stenosis;

(b) introducing a first change in a blood property in a blood flow outside the catheter and upstream of the blood property sensor;

(c) detecting passage of the first change in the blood property at the blood property sensor;

(d) reducing the stenosis of in the vessel;

(e) introducing a second change in the blood property upstream of the sensor;

(f) detecting passage of the second change in the blood property at the blood property sensor; and

(g) determining a change in blood flow corresponding to the detected passage of the first change in the blood property and the second change in the blood property.

17. The method of Claim 16, wherein inserting a catheter and a blood property sensor into a vessel includes inserting a first catheter having a stenosis reducing member and a second catheter having the blood property sensor.

18. The method of Claim 16, wherein inserting a catheter and a blood property sensor into a vessel includes inserting a catheter having a stenosis reducing member and the blood property sensor.

19. (Twice Amended) A method of monitoring blood flow during a vascular corrective procedure, comprising:

(a) inserting a catheter into a vessel;

(b) employing the catheter to perform a vascular correction in the vessel;

(c) introducing a first blood property change into a blood flow outside the catheter;

(d) detecting passage of the first blood property change past a downstream sensor on the catheter; and

(e) calculating the blood flow in response to the change in blood property and passage of the blood property past the downstream sensor.

20. (Twice Amended) An apparatus for determining blood flow in a vascular passage, comprising:

(a) a catheter having means for increasing the effective size of a portion of the vascular passage, the catheter including a dilution indicator introduction port located to pass a dilution indicator from the catheter and a downstream blood property sensor; and

(b) a controller operably connected to the blood property sensor for calculating a flow through the vascular passage corresponding to a signal from the blood property sensor.

21. The apparatus of Claim 20, wherein the controller determines the flow corresponding to the relation $AF = \frac{V}{\int C(t)dt}$ where AF corresponds to the flow, V is a volume of indicator introduced and $\int C(t)dt$ is the area under a dilution curve.

22. (Once Amended) An apparatus for determining an intra-procedural blood flow in a ~~vascular~~ corrective procedure, comprising:

(a) a catheter;

(b) a blood parameter altering section on the catheter located to alter a blood parameter external to the catheter;

(c) means for effecting the corrective produce; and

(d) a blood parameter sensor connected to the catheter and spaced from the blood parameter altering section to sense the altered blood parameter external to the catheter.

23. The apparatus of Claim 22, wherein the blood altering section includes one of a port and a temperature gradient generator.

24. The apparatus of Claim 22, further comprising a controller connectable to the altering section and the blood parameter sensor to calculate the blood flow.

25. (Once Amended) A method of monitoring a stenosis reducing procedure in a vessel, comprising:

(a) locating a blood parameter altering section in the vessel to alter a blood parameter in a blood flow contacting the vessel;

(b) locating a blood parameter sensor downstream of the altering section;

(c) performing the stenosis reducing procedure; and

(d) determining a blood flow in response to a passage of an altered blood property past the blood parameter sensor.

26. The method of Claim 25, wherein performing the stenosis reducing procedure includes angioplasty.

27. The method of Claim 25, further comprising locating the blood parameter sensor to reduce wall effects from the vessel.

28. The method of Claim 25, further comprising rotating the blood parameter sensor with respect to the vessel to reduce wall effects from the vessel.

29. The method of Claim 25, further comprising locating a plurality of blood parameter sensors in the vessel.

30. The apparatus of Claim 1, wherein the sensor detects changes in one of electrical impedance and electrical resistance.

31. The apparatus of Claim 1, wherein the sensor detects one of an optical, thermal, electrical, chemical or physical property of the blood.

32. The catheter of Claim 9, wherein the sensor detects changes in one of electrical impedance and electrical resistance.

33. The catheter of Claim 9, wherein the sensor detects one of an optical, thermal, electrical, chemical or physical property of the blood.

Please add the following new claims:

34. (New) An apparatus for determining a blood flow in a vessel, comprising:

(a) an elongate catheter having a stenosis reducing member, a blood property change port located to alter a blood property outside the catheter and a downstream sensor spaced from the port for producing a signal corresponding to the blood property in a blood flow in the vessel, and the correspondence relates blood

flow to $= \frac{V}{\int C(t)dt}$ where V is the volume of indicator introduced and $\int C(t)dt$ is an area under a dilution curve..

35. (New) An apparatus for determining blood flow in a vascular passage, comprising:

(a) a catheter having means for increasing the effective size of a portion of the vascular passage, the catheter including a dilution indicator introduction port and a downstream blood property sensor; and

(b) a controller operably connected to the blood property sensor for calculating a blood flow through the vascular passage corresponding to a signal from the blood property sensor and corresponding to the relation $AF = \frac{V}{\int C(t)dt}$ where AF corresponds to the blood flow, V is a volume of indicator introduced and $\int C(t)dt$ is the area under a dilution curve..